

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICATION NUMBER: **10/561,618**
FILING DATE: **05/05/2006**
FIRST NAMED INVENTOR: **Brenda F. Baker**
ART UNIT: **1635**
EXAMINER NAME: **Tracy Ann Vivlemore**
ATTORNEY DOCKET NUMBER: **CORE0005USA**
TITLE: **OLIGOMERIC COMPOUNDS FOR USE
IN GENE MODULATION**

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ALEXANDRIA, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT
Under 37 C.F.R. §§ 1.56 and 1.97-98

SIR:

Pursuant to the provisions of 37 C.F. R. §§ 1.56 and 1.97-98, enclosed herewith is PTO Form PTO/SB/08A and PTO/SB/08B listing references for consideration by the Examiner.

The filing of this Information Disclosure Statement shall not be construed as a representation regarding the completeness of the list of references, or that inclusion of a reference in this list is an admission that it is prior art or is pertinent to this application, or that a search has been made, or as an admission that the information listed is, or may be considered to be, material to patentability, or that no other material information exists, and shall not be construed as an admission against interest in any manner.

This Information Disclosure Statement is being filed:

☒ within three months of the filing date of the application, or date of entry into the national stage of an international application, or before the mailing date of a first office action on the merits, whichever event last occurred;

☐ before the mailing of a first official action after filing of a request for continued examination (RCE) under 37 C.F.R. § 1.114;

☐ after three months of the filing date of this national application or the date of entry of the national stage in an international application, or after the mailing date of the first official action on the merits, whichever event last occurred, but before that mailing date of the first office action to occur of either: (1) a final action under 37 C.F.R. § 1.113; or (2) an action that otherwise closes prosecution in the application, and:

☐ attached hereto is the fee set forth under 37 C.F.R. § 1.17(p) for submission of this Information Disclosure Statement under 37 C.F.R. § 1.97(c); OR

☐ Applicant certifies pursuant to 37 C.F.R. § 1.97(e) that:

☐ each item of the information contained in this Information Disclosure Statement was first cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Statement;

OR

☐ no item of information contained in this Information Disclosure Statement was cited in a counterpart foreign application and, to the knowledge of the person signing this certification after making reasonable inquiry, no item of information contained in this Statement was known to any individual designated under 37 C.F.R. § 1.56(c) more than three months prior to the filing of this Statement.

☐ on or before the payment of the issue fee but after the mailing date of the first to occur of either: (1) a final action under 37 C.F.R. § 1.113; (2) a notice of allowance under 37 C.F.R. § 1.311; or (3) an action that otherwise closes prosecution in the application, and:

☐ Applicant certifies pursuant to 37 C.F.R. § 1.97(e) that:

☐ each item of information contained in this Information Disclosure Statement was cited in a communication from a foreign

patent office in a counterpart foreign application not more than three months prior to the filing of this statement;

OR

☐ no item of information contained in this Information Disclosure Statement was cited in a counterpart foreign application and, to the knowledge of the person signing this certification after making reasonable inquiry, no item of information contained in this Statement was known to any individual designated under 37 C.F.R. § 1.56(c) more than three months prior to the filing of this Statement. AND

☐ attached hereto is the fee set forth under 37 C.F.R. § 1.17(p) for submission of this Information Disclosure Statement under 37 C.F.R. § 1.97(c); OR

☐ after the payment of the issue fee. Applicant requests that the information contained in this Information Disclosure Statement be placed in the file according to 37 C.F.R. § 1.97(i), although the information may not be considered by the USPTO.

☒ Enclosed is a copy of each listed reference that may be material to the examination of this application, and for which there may be a duty to disclose.

☐ This application relies, under 35 U.S.C. § 120, on the earlier filing date of prior application No. , filed on , and the references cited therein are hereby referenced, but are not required to be provided in this application under 37 C.F.R. § 1.98(d).

☒ This application was filed after June 30, 2003. Therefore, pursuant to the waiver of the requirements under 37 C.F.R. § 1.98(a)(2)(i), copies of each U.S. Patent and each U.S. Patent Application Publication are not required to be submitted. Copies of any foreign patent documents and non-patent literature cited herein are enclosed.

☐ Each item of information contained in this Information Disclosure Statement was cited in the communication from a foreign patent office in a counterpart application, and the communication was not received by any individual designated in 37 C.F.R. § 1.56(c)

more than thirty days prior to the filing of this Information Disclosure Statement 37 C.F.R. § 1.704(d).

☒ Applicant submits that no fee is required for the consideration of this Information Disclosure Statement. However, if a fee is due, the Commissioner is hereby authorized to charge Deposit Account No 500252 referencing case number CORE0005USA. Consideration of the listed references and favorable action are solicited.

Respectfully submitted,



Robert S. Andrews
Registration No.: 44,508
Isis Pharmaceuticals, Inc.
1896 Rutherford Road
Carlsbad, CA 92008

Dated: 8-8-06

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1 of 5

Complete if Known

Application Number 10/561,618
 Filing Date 05/05/2006
 First Named Inventor Brenda F. Baker
 Art Unit 1635
 Examiner Name Tracy Ann Vivlenore
 Attorney Docket Number CORE0006/USA

U.S. PATENT DOCUMENTS

| Examiner Initials * | Cite No. ¹ | Document Number | | Publication/Issue Date MM-DD-YYYY | Name of Patentee or Applicant of Cited Document | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear |
|---------------------|-----------------------|--|--|-----------------------------------|---|---|
| | | Number - Kind Code ² (if known) | | | | |
| | AA | US-5,484,908 | | 01-16-1996 | Fruehler et al. | |
| | AB | US-5,898,031 | | 04-29-1999 | Crooke | |
| | AC | US-6,905,087 | | 12-21-1999 | Cook et al. | |
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| | AE | US-2004/0259247 | | 12-23-2004 | Tuschl et al. | |
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FOREIGN PATENT DOCUMENTS

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|---------------------|-----------------------|---|--|---|---|---|----|
| | | Country Code ³ - Number ⁴ - Kind Code ⁵ (if known) | | | | | |
| | AF | WO 99/32619 A1 | | 07-01-1999 | Carnegie Institute | | |
| | AG | WO 00/44895 A1 | | 08-03-2000 | Kreutzer et al. | | |
| | AH | WO 00/44914 A1 | | 08-03-2000 | Medical College | | |
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| | AN | WO 01/48183 A2 | | 07-05-2001 | Deven NV | | |
| | AO | WO 01/75164 A2 | | 10-11-2001 | Whitehead Inst. | | |

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| Examiner Signature | Date Considered |
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*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 608. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹ Applicant's unique citation designation number (optional). ² See Kinda Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language translation is attached.

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 2 of 5

Complete if Known

Application Number 10/561,618
Filing Date 05/05/2006
First Named Inventor Brenda F. Baker
Art Unit 1635
Examiner Name Tracy Ann Vivimore
Attorney Docket Number CORE0005USA

NON PATENT LITERATURE DOCUMENTS

| Examiner Initials * | Cite No. 1 | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | T 2 |
|---------------------|------------|---|-----|
| AP | | BASS, B. L., "Double-Stranded RNA as a Template for Gene Silencing," <i>Cell</i> (2000) 101(3):235-238. | |
| AQ | | BOUTLA A. et al., "Short 5'-phosphorylated double-stranded RNAs induce RNA interference in <i>Drosophila</i> ," <i>Current Biology</i> (2001) 11(22):1776-1780. | |
| AR | | BRAASCH, D. A. et al., "RNA Interference in Mammalian Cells by Chemically-Modified RNA," <i>Biochemistry</i> (2003) 42(26):7967-7975. | |
| AS | | BRANTL, S., "Antisense-RNA regulation and RNA interference," <i>Biochimica et Biophysica Acta</i> (2002) 1575(1-3):15-25. | |
| AT | | BUHR, C. A. et al., "Oligodeoxynucleotides containing C-7 propyne analogs of 7-deaza-2'-deoxyguanosine and 7-deaza-2'-deoxyadenosine," <i>Nucleic Acids Research</i> (1996) 24(15):2974-2980. | |
| AU | | CHIU, Y.-L. et al., "siRNA function in RNAi: A chemical modification analysis," <i>RNA</i> (2003) 9(9):1034-1048. | |
| AV | | COGONI, C. et al., "Post-transcriptional gene silencing across kingdoms," <i>Curr Opin Genet Dev.</i> (2000) 10(6):638-643. | |
| AW | | ELBASHIR, S. M. et al., "RNA interference is mediated by 21- and 22-nucleotide RNAs," <i>Genes Dev.</i> (2001) 15(2):188-200. | |
| AX | | ELBASHIR, S. M. et al., "Duplexes of 21-nucleotide RNAs mediate RNA interference in cultured mammalian cells," <i>Nature</i> (2001) 411(6836):494-498. | |
| AY | | ELBASHIR, S. M. et al., "Functional anatomy of siRNAs for mediating efficient RNAi in <i>Drosophila melanogaster</i> embryo lysate," <i>EMBO</i> (2001) 20(23):6877-6887. | |
| AZ | | FIRE, A. et al., "Potent and specific genetic interference by double-stranded RNA in <i>Caenorhabditis elegans</i> ," <i>Nature</i> (1998) 391:806-811. | |
| BA | | GALLO, M. et al., "2'-C-Methyluridine phosphoramidite: a new building block for the preparation of RNA analogues carrying the 2'-hydroxyl group," <i>Tetrahedron</i> (2001) 57(27):5707-5713. | |
| BB | | GUILLERM, D. et al., "Synthesis of 4'-fluoroadenosine as an inhibitor of S-adenosyl-L-homocysteine hydrolase," <i>Bioorganic & Medicinal Chemistry Letters</i> (1995) 5(14):1455-1460. | |
| BC | | GUO, S. et al., "par-1, a Gene Required for Establishing Polarity in <i>C. elegans</i> Embryos, Encodes a Putative Ser/Thr Kinase That Is Asymmetrically Distributed," <i>Cell</i> (1995) 81(4):611-620. | |

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| Examiner Signature | Date Considered |
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 3 of 5

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| Application Number | 10/561,618 |
| Filing Date | 05/05/2006 |
| First Named Inventor | Brenda F. Baker |
| Art Unit | 1635 |
| Examiner Name | Tracy Ann Vivimore |
| Attorney Docket Number | CORE0005USA |

NON PATENT LITERATURE DOCUMENTS

| Examiner Initials * | Cite No. ¹ | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | T ² |
|---------------------|-----------------------|---|----------------|
| | BD | GURU, T., "A silence that speaks volumes," <i>Nature</i> (2000) 404:804-808. | |
| | BE | GUTIERREZ, A. J. et al., "Antisense Gene Inhibition by C-5-Substituted Deoxyuridine-Containing Oligodeoxynucleotides," <i>Biochemistry</i> (1997) 36(4):743-748. | |
| | BF | HARRY O'KURU, R. E. et al., "A Short, Flexible Route toward 2'-C-Branched Ribonucleosides," <i>J. Org. Chem.</i> (1997) 62(6):1754-1759. | |
| | BG | JACOBSON, K. A. et al., "Methanocarba Analogues of Purine Nucleosides as Potent and Selective Adenosine Receptor Agonists," <i>J. Med. Chem.</i> (2000) 43(11):2196-2203. | |
| | BH | JORGENSEN, R. A. et al., "Chalcone synthase cosuppression phenotypes in petunia flowers: comparison of sense vs. antisense constructs and single-copy vs. complex T-DNA sequences," <i>Plant Mol. Biol.</i> (1996) 31(5):957-973. | |
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| | BL | LEE, K. et al., "Ring-Constrained (N)-Methanocarba Nucleosides as Adenosine Receptor Agonists: Independent 5'-Uronamide and 2'-Deoxy Modifications," <i>Bioorganic & Medicinal Chemistry Letters</i> (2001) 11(10):1333-1337. | |
| | BM | LIN, K.-Y. et al., "A Cytosine Analogue Capable of Clamp-Like Binding to a Guanine in Helical Nucleic Acids," <i>J. Am. Chem. Soc.</i> (1998) 120(33):8531-8532. | |
| | BN | MARTINEZ, J. et al., "Single-Stranded Antisense siRNAs Guide Target RNA Cleavage in RNAi," <i>Cell</i> (2002) 110(5):563-574. | |
| | BO | MELLITZER, G. et al., "Spatial and temporal 'knock down' of gene expression by electroporation of double-stranded RNA and morpholinos into early postimplantation mouse embryos," <i>Mechanisms of Development</i> (2002) 118(1-2):57-63. | |
| | BP | MONTGOMERY, M. K. et al., "RNA as a target of double-stranded RNA-mediated genetic interference in <i>Caenorhabditis elegans</i> ," <i>Proc. Natl. Acad. Sci. USA</i> (1998) 95(26):15502-15507. | |

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 4 of 5

Complete If Known

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|------------------------|--------------------|
| Application Number | 10/561,818 |
| Filing Date | 05/05/2006 |
| First Named Inventor | Brenda F. Baker |
| Art Unit | 1635 |
| Examiner Name | Tracy Ann Vivimore |
| Attorney Docket Number | CORE0005USA |

NON PATENT LITERATURE DOCUMENTS

| Examiner Initials * | Cite No. 1 | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | T 2 |
|---------------------|------------|---|-----|
| | BQ | MORITA, K. et al., "2'-O,4'-C-Ethylene-Bridged Nucleic Acids (ENA): Highly Nuclease-Resistant and Thermodynamically Stable Oligonucleotides for Antisense Drug," <i>Bioorganic & Medicinal Chemistry Letters</i> (2002) 12(1):73-76. | |
| | BR | MOULDS, C. et al., "Site and Mechanism of Antisense Inhibition by C-5 Propyne Oligonucleotides," <i>Biochemistry</i> (1995) 34(15):5044-5053. | |
| | BS | NAPOLI, C. et al., "Introduction of a Chimeric Chalcone Synthase Gene into Petunia Results in Reversible Co-Suppression of Homologous Genes in trans," <i>Plant Cell</i> (1990) 2(4):279-289. | |
| | BT | NISHIKURA, K. et al., "A Short Primer on RNAi: RNA-Directed RNA Polymerase Acts as a Key Catalyst," <i>Cell</i> (2001) 107(4):415-418. | |
| | BU | OWEN, G. R. et al., "4-Substituted Nucleosides. 3. Synthesis of Some 4'-Fluorouridine Derivatives," <i>J. Org. Chem.</i> (1976) 41(18):3010-3017. | |
| | BV | PARRISH, S. et al., "Functional Anatomy of a dsRNA Trigger: Differential Requirement for the Two Trigger Strands in RNA Interference," <i>Molecular Cell</i> (2000) 6(5):1077-1087. | |
| | BW | SCHWARZ, D. S. et al., "Evidence that siRNAs Function as Guides, Not Primers, in the <i>Drosophila</i> and Human RNAi Pathways," <i>Molecular Cell</i> (2002) 10(3):537-548. | |
| | BX | SCHWARZ, D. S. et al., "Asymmetry in the Assembly of the RNAi Enzyme Complex," <i>Cell</i> (2003) 115(2):199-208. | |
| | BY | SOUTSCHEK, J. et al., "Therapeutic silencing of an endogenous gene by systemic administration of modified siRNAs," <i>Nature</i> (2004) 432(7014):173-178. | |
| | BZ | SINGH, S. K. et al., "LNA (locked nucleic acids): synthesis and high-affinity nucleic acid recognition," <i>Chem Commun</i> (1998) (4):455-456. | |
| | CA | TABARA, H. et al., "RNAi in <i>C. elegans</i> : Soaking in the Genome Sequence," <i>Science</i> (1998) 282(5388):430-431. | |
| | CB | TANG, X.-Q. et al., "2'-C-Branched Ribonucleosides: Synthesis of the Phosphoramidite Derivatives of 2'-C-Methylcytidine and Their Incorporation into Oligonucleotides," <i>J. Org. Chem.</i> (1999) 64(3):747-754. | |
| | CC | TJSTERMAN, M. et al., "RNA Helicase MUT-14-Dependent Gene Silencing Triggered in <i>C. elegans</i> by Short Antisense RNAs," <i>Science</i> (2002) 295(5555):694-697. | |
| | CD | TIMMONS, L. et al., "Specific interference by ingested dsRNA," <i>Nature</i> (1998) 395(6705):854. | |

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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

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| Sheet | 5 | of | 5 |
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NON PATENT LITERATURE DOCUMENTS

[illegible]Examiner
Signature

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